

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Richmond Division

DR. TIMOTHY BAXTER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 3:23-cv-92 (RCY)
	)	
XAVIER BECERRA, <i>in his official</i>	)	
<i>capacity as Secretary, Department of</i>	)	
<i>Health and Human Services,</i>	)	
	)	
and	)	
	)	
CHRISTI A. GRIMM, <i>in her official</i>	)	
<i>capacity as Inspector General of the</i>	)	
<i>United States Department of Health</i>	)	
<i>and Human Services,</i>	)	
	)	
Defendants.	)	
	)	

**MEMORANDUM OPINION**

This is a lawsuit challenging an action by a federal agency. Plaintiff Dr. Timothy Baxter (“Dr. Baxter” or “Plaintiff”) commenced this litigation to appeal his five-year mandatory exclusion from federally funded health care programs handed down by the Secretary of the Department of Health and Human Services (“HHS Secretary” or “the Secretary”).

This case is currently before the Court on the parties’ cross-motions for summary judgment. The matters have been fully briefed, and the Court dispenses with oral argument because the materials before it adequately present the facts and legal contentions, and argument would not aid the decisional process. E.D. Va. Loc. Civ. R. 7(J). For the reasons stated below, the Court finds no reversible error committed by the Department of Health and Human Services

(“HHS” or “the Agency”). The Court thus will grant the Defendants’ Motion for Summary Judgement and will deny Plaintiff’s cross-motion for the same.

### I. STANDARD OF REVIEW

This Court reviews the HHS Secretary’s exclusion decisions to determine “whether the findings of the Secretary are supported by substantial evidence and whether the correct law was applied.” *Hays v. Sullivan*, 907 F.2d 1453, 1456 (4th Cir. 1990) (citing 42 U.S.C. § 405(g)); *accord Friedman v. Sebelius*, 686 F.3d 813, 818 (D.C. Cir. 2012); *see also* 42 U.S.C. § 1320a–7(f) (providing for review pursuant to 42 U.S.C. § 405(g) of the Secretary’s decision to exclude an individual). This Court also reviews the Secretary’s exclusion decisions according to the arbitrary and capricious standard of the Administrative Procedure Act (“APA”). *See* 5 U.S.C. § 706(2)(A); *Friedman*, 686 F.3d at 826–27 (positing that neither 42 U.S.C. §§ 1320a–7(f)(1) nor 405(g) preclude arbitrary and capricious review under the APA); *see also Nader v. Hargan*, 721 F. App’x 287 (4th Cir. 2018) (applying APA legal standard to Secretary’s legal conclusions despite applicability of 42 U.S.C. § 405(g) via 42 U.S.C. § 1395ff(b)(1)(A)).<sup>1</sup>

In a suit challenging agency action, “review is limited to the administrative record and ‘resolution . . . does not require fact finding on behalf of [the] court.’” *Hyatt v. U.S. Pat. & Trademark Off.*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015) (alterations in original) (quoting *Nw. Motorcycle Ass’n v. U.S. Dep’t of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994)); *see also Camp v. Pitts*, 411 U.S. 138, 142 (1973) (“focal point” for judicial review of agency action is “the administrative record already in existence, not some new record made initially in the reviewing court”). “Accordingly, the ordinary summary judgment standard under [Federal Rule of Civil

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<sup>1</sup> The Secretary’s position is that the APA’s arbitrary and capricious standard is inapplicable where 42 U.S.C. § 405(g) applies. *See* Gov’t’s Resp. 9 n.5. Given the cited authority, the Court cannot agree.

Procedure 56(c)] does not apply” because “the presence or absence of a genuine dispute of material fact is not in issue, as the facts are all set forth in the administrative record.” *Hyatt*, 146 F. Supp. 3d at 780. Therefore, when a party seeks review of agency action, “the district judge sits as an appellate tribunal,” and “[t]he ‘entire case’ on review is a question of law.” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001).

## II. BACKGROUND

### A. Factual Background

The Court has concluded that the following factual narrative, drawn from the administrative record before the Agency, represents the undisputed facts for the purpose of resolving the cross-motions for summary judgment:

#### 1. Reckitt Benckiser Pharmaceuticals, Inc.’s Suboxone Tablets

In October 2002, Reckitt Benckiser Pharmaceuticals, Inc. (“RPB”) received approval from the U.S. Food and Drug Administration (“FDA”) for two drugs: the Suboxone Sublingual Tablet (“Suboxone Tablet”) and Subutex Sublingual Tablet (“Subutex Tablet”) (collectively, the “Tablets”). *See* AR<sup>2</sup> 540, ¶ 10 (Criminal Information, *United States v. Baxter*, No. 1:20-cr-32 (W.D. Va. Aug. 29, 2020), ECF No. 1 (hereinafter, “Information”)).<sup>3</sup> Both drugs came in tablet form and contained buprenorphine, an opioid partial agonist and Schedule III controlled substance, and were designed to treat opioid addiction and dependence. *Id.* ¶¶ 9–10. The FDA also approved orphan-drug exclusivity for the Tablets, meaning that the FDA was prohibited from approving any competing application for buprenorphine for the same indication for seven years. *Id.* ¶ 10.

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<sup>2</sup> All cites to “AR” are to the Administrative Record, filed at ECF Nos. 20 (AR Part I) and 21 (AR Parts II–IV). The Court cites the AR according to the Bates-style numbering that appears in the bottom left of each record page, first appearing on page 5 of ECF No. 20 (AR Part I). AR Part I spans pages 001–244; AR Part II spans pages 245–499; AR Part III spans pages 500–693; and AR Part IV spans pages 694–779.

<sup>3</sup> In his plea agreement, Dr. Baxter admitted that “all of the facts set forth in the Information are true and correct.” AR 550 (Plea Agreement, *United States v. Baxter*, 1:20-cr-32 (W.D. Va. Aug. 29, 2020), ECF No. 3).

## 2. Dr. Baxter's Career at RPB and Suboxone Film

Dr. Baxter became RPB's global medical director in 2006. AR 054 (Dr. Baxter's Notice of Appeal and Request for Hearing before ALJ). Among other responsibilities, Dr. Baxter "presided over" RPB's "medical information group—a team of medical professionals who were charged with answering medical questions about pharmacology, and medical affairs activities." AR 454, ¶ 15 (Compl., *Baxter v. Becerra, et al.*, No. 1:21-cv-451 (E.D. Va. Apr. 13, 2021), ECF No. 1). Dr. Baxter thus "advise[d]" people who had "the authority to make commercial decisions . . . regarding medical issues and patient safety." *Id.* ¶ 16.

In 2007, as Suboxone Tablet and Subutex Tablet were nearing the end of their exclusivity period, RPB began developing a new drug for use in opioid addiction/dependence treatment, Suboxone Sublingual Film ("Suboxone Film"). AR 541, ¶¶ 13–14 (Information). Like Suboxone Tablet, Suboxone Film contained buprenorphine with naloxone, which can cause withdrawal symptoms when injected. AR 540–41, ¶¶ 11, 14. In contrast, Subutex Tablet did not contain naloxone. AR 541, ¶ 12. As the name suggests, Suboxone Film was not a tablet, but was a film formulation with some patented aspects. *Id.* ¶ 14. Suboxone Film also came packaged in wrapped foil pouches, while the Tablets usually came in bottles with caps. AR 540–41, ¶¶ 11–12, 14.

Suboxone Film obtained FDA approval in August 2010. AR 541, ¶ 15. At that time and up until at least 2020, Suboxone Film and the Tablets generated substantially all of RPB's revenue. AR 542, ¶ 19. But after Suboxone Film received FDA approval, RPB actively promoted only Suboxone Film. *Id.*

In June 2012, Dr. Baxter approved a contract with the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") to analyze exposure data from poison control centers regarding the risk of unintended pediatric exposure for buprenorphine drugs. AR

542–43, ¶¶ 18, 22. Dr. Baxter directly managed the RPB employee who was RPB’s point of contact with respect to RADARS’ pediatric exposure analysis projects in 2012, RPB’s Medical Affairs Manager, Dr. Jane Ruby. AR 542, ¶ 18; AR 254 (Dr. Baxter’s Notice of Appeal and Opening Brief to Departmental Appeals Board (hereinafter, “Notice of Appeal to DAB”)). RPB used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film. AR 542, ¶ 19 (Information).

### 3. The Distribution of False and Misleading Data to MassHealth

In September 2012, Dr. Ruby informed Dr. Baxter and others that a representative of the Massachusetts Medicaid program (“MassHealth”) had requested a meeting. AR 543 ¶, 23. At the time, MassHealth was the largest Medicaid program in the country by volume of addiction-treatment-drug business—but it did not list Suboxone Film as a preferred drug on its formulary and restricted approval of Suboxone Film for reimbursement. AR 542, ¶ 20. Dr. Ruby stated that she was “very excited” “to share the pediatric data” RADARS had gathered with the MassHealth official. AR 543, ¶ 23. Dr. Ruby “assured” Dr. Baxter and others that “things will change in Massachusetts.” *Id.*

Dr. Ruby met with MassHealth’s Pharmacy Director Dr. Paul Jeffrey on October 9, 2012. AR 543–44, ¶ 24; AR 254 (Notice of Appeal to DAB). Dr. Ruby reported to Dr. Baxter and others that Dr. Jeffrey was “very responsive” to the pediatric-exposure data. AR 543–44, ¶ 24 (Information). Dr. Ruby advised Dr. Baxter that she had asked RADARS for a Massachusetts-specific analysis of unintended pediatric exposure to send to the MassHealth official and opined that the exposure rates in Massachusetts would track the “high” “utilization of tablets” there. *Id.*

On October 10, 2012, RADARS responded with the Massachusetts-specific data Dr. Ruby had requested. AR 544, ¶ 25. Contrary to what Dr. Ruby expected, Suboxone Film did not have

the lowest exposure rate—instead, buprenorphine-only tablets (such as Subutex) had the lowest rate of unintended pediatric exposure (1.8 exposures per 10,000 unique recipients). AR 544–45, ¶¶ 25, 28. Suboxone Film was in the middle (2.7 exposures per 10,000 unique recipients), and Suboxone Tablets was highest (3.3 exposures per 10,000 unique recipients). AR 544, ¶ 25.

If the exposure rates for the two forms of Tablets were added, however, the combined tablet rate appeared higher than Suboxone Film’s exposure rate. *Id.* Dr. Ruby emailed RADARS, copying Dr. Baxter, asking: could she “just add the [Tablets’ rates] to see the difference from [Suboxone Film]?” AR 544–45, ¶ 26. Dr. Baxter responded to this email, to Dr. Ruby only, seeking confirmation of his perception that RADARS’s data “actually appear[ed] to make [buprenorphine-only] tablets look best or am I mi[s]-reading?” *Id.* (first and third alterations in original). RADARS replied to Dr. Ruby, copying Dr. Baxter, that they would follow up with the additional calculations sought. *Id.*

In an October 16, 2012 email, Dr. Ruby combined the Tablets’ exposure rates as she had proposed and sent that data to MassHealth’s Dr. Jeffrey, representing to MassHealth that Suboxone Film had a lower pediatric-exposure rate than the Tablets. *Id.* ¶ 27. This was false and misleading: it was inaccurate to simply add the two Tablets’ exposure rates together. *Id.* Further, Dr. Ruby indicated that she had received the data from RADARS when, in fact, she had not received it from RADARS, but had done the calculations herself. *Id.* Dr. Ruby then forwarded her email to Dr. Baxter, stating that she sent it to the MassHealth official with the hope that it would “help us get some movement in Mass.” *Id.* Dr. Baxter did not respond to this email. *Id.*

On November 19, 2012, Dr. Ruby responded to a follow-up question from MassHealth’s Dr. Jeffrey about Dr. Ruby’s false and misleading October 16 email by sending him a chart comparing pediatric exposure rates of Suboxone Film and Suboxone Tablets. AR 545–46, ¶ 28.

The chart indicated that Suboxone Film had a substantially lower rate of pediatric exposure than Suboxone Tablets. *Id.* But the chart contained lines only for “Tablets” and “Oral Film;” a third line pertaining to buprenorphine-only tablets (such as Subutex), with a rate closer to that of Suboxone Film, was omitted. *Id.* This chart thus reinforced the false and misleading claim in Dr. Ruby’s email that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts. *Id.* In light of the previous false and misleading email, the chart without the third line “failed to reveal facts material to MassHealth prior to its updated formulary decision.” *Id.* Dr. Baxter was not copied on that email, but around the same time, another employee emailed Dr. Baxter asking whether they could use a chart that likewise “did not show the [buprenorphine-only tablets] line” and commenting how “[t]hat would make such a huge difference!” *Id.* Dr. Baxter replied: “That chart is now published so knock [sic] yourself out!” *Id.* Dr. Ruby subsequently received additional data that again did not show that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, but she did not share that data with Dr. Jeffrey at MassHealth. AR 546, ¶ 29.

In December 2012, MassHealth announced that it would provide access to the unit-dosed formulation of Suboxone Film for households with children less than six years of age. AR 546–47, ¶ 30. Dr. Baxter did not approve sending a correction letter to MassHealth until December 2015—three years after the misrepresentations and two years after the government’s investigation had begun. AR 547, ¶ 31.

RBP demerged from its parent company, Reckitt Benckiser Group, and became Indivior Inc. (“Indivior”), a subsidiary of Indivior PLC, in December 2014. AR 538, ¶ 3. Dr. Baxter then became Indivior PLC’s chief medical officer, a role he held until he left in March of 2016. *Id.*

#### 4. Dr. Baxter's Prosecution and Conviction Under 21 U.S.C. § 331(a)

In August of 2020, Dr. Baxter, as a responsible corporate officer,<sup>4</sup> pleaded guilty in the United States District Court for the Western District of Virginia to one misdemeanor count of misbranding a drug in violation of 21 U.S.C. § 331(a).<sup>5</sup> AR 549–59 (Plea Agreement, *United States v. Baxter*, 1:20-cr-32 (W.D. Va. Aug. 29, 2020), ECF No. 3 (hereinafter, “Plea Agreement”)). The factual basis for the plea was the series of false and misleading statements regarding Suboxone Film and the unintended pediatric exposure data provided by Dr. Baxter's direct subordinate, Dr. Ruby, to MassHealth's Pharmacy Director Dr. Jeffrey in October and November 2012, and Dr. Baxter's failure to prevent and promptly correct those false and misleading statements and claims. AR 542–47 (Information). As part of his plea, Dr. Baxter acknowledged that he could be “excluded pursuant to 42 U.S.C. § 1320a-7, from participation in Medicare, Medicaid, and all other Federal health care programs.” AR 553 (Plea Agreement). The court accepted Dr. Baxter's plea and he was adjudged guilty of misbranding. *See* AR 561 (Judgement, *United States v. Baxter*, 1:20-cr-32 (W.D. Va. Dec. 17, 2020), ECF No. 32).

Dr. Baxter was sentenced to one year of probation, with six months to be served in home confinement, and the statutory maximum \$100,000 fine. AR 562, 565. Dr. Baxter was not required to pay any form of restitution. AR 561–66. At sentencing, Dr. Baxter's attorney

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<sup>4</sup> Under the “responsible corporate officer” (“RCO”) doctrine, a “corporate agent, through whose act, default, or omission the corporation committed a crime” in violation of the Food, Drug, and Cosmetic Act may be held criminally liable for the wrongdoing of the corporation “whether or not the crime required ‘consciousness of wrongdoing’” by the agent. *United States v. Park*, 421 U.S. 658, 670 (1975). Criminal liability under the RCO doctrine extends “not only to those corporate agents who themselves committed the criminal act, but also to those who by virtue of their managerial positions or other similar relation to the actor could be deemed responsible for its commission.” *Id.* Though the general tenor of Dr. Baxter's briefs emits a distaste for the RCO doctrine, Dr. Baxter accurately recognizes that “the relative wisdom of the RCO doctrine is not at issue here, nor is the propriety of Dr. Baxter's conviction[.]” Pl.'s Mem. Supp. 1, ECF No. 23.

<sup>5</sup> 21 U.S.C. § 331 (a) prohibits “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.” A drug is “misbranded” if “its labeling is false or misleading in any particular.” 21 U.S.C. § 352(a).



acknowledged that they likely would “be spending the first part of next year arguing about whether or not he should be excluded” under 42 U.S.C. § 1320a-7. AR 607 (Sent’g Hr’g Tr., *United States v. Baxter*, 1:20-cr-32 (W.D. Va. Feb. 2, 2021), ECF No. 58).

5. 42 U.S.C. § 1320a-7 and the Administrative Process

The statute at the heart of this dispute is 42 U.S.C. § 1320a-7. As the Fourth Circuit has recognized, the statute represents a Congressional effort “to combat waste, fraud, and abuse in health insurance and health care delivery,” “to protect federal programs from untrustworthy individuals[,] and to provide a clear and strong deterrent against the commission of criminal acts.” *Morgan v. Sebelius*, 694 F.3d 535, 538 (4th Cir. 2012) (per curiam) (internal quotation marks omitted).

In line with these purposes, 42 U.S.C. § 1320a-7 authorizes, and in some cases requires, that certain individuals and entities be excluded from participating in federal health care programs. The statute requires the HHS Secretary to exclude individuals that have been convicted of certain enumerated offenses. *See* 42 U.S.C. § 1320a-7(a). Relevant here, the Secretary “shall” exclude “[a]ny individual or entity that has been convicted of a criminal offense related to the delivery of an item or service” under Medicare or “under any State health care program.” *Id.* § 1320a-7(a)(1); *see also* 42 C.F.R. § 1001.101. For such mandatory exclusions, the statutory minimum exclusion period is five years. 42 U.S.C. § 1320a-7(c)(3)(B). The statute also enumerates grounds for permissive exclusion—i.e., exclusion at the Secretary’s discretion. *Id.* § 1320a-7(b). The permissive exclusion period is three years unless the Secretary determines (pursuant to published regulations) that specific mitigating or aggravating circumstances apply. *Id.* § 1320a-7(c)(3)(D). An excluded individual or entity is entitled to notice, the ability to appeal the exclusion through an

administrative process, and judicial review once the administrative proceedings are complete. *Id.* § 1320a-7(f).

The Secretary has delegated responsibility for implementing exclusions to the HHS Office of Inspector General (“HHS-OIG”). 48 Fed. Reg. 21662 (May 13, 1983). Once HHS-OIG makes a determination about whether exclusion is appropriate, HHS-OIG notifies individuals subject to the five-year mandatory exclusion by written notice, which sets out, among other things, the basis, length, and effect of the exclusion, as well as an individual’s appeal rights. 42 C.F.R. § 1001.2002. The exclusion begins 20 days after the date of the notice. *Id.* § 1001.2002(b). The excluded individual or entity has the right to appeal the exclusion and request a hearing before an HHS administrative law judge (“ALJ”) within 60 days of receiving the notice of exclusion. *Id.* § 1001.2007, 1005.2. After the ALJ issues a final decision, an excluded individual may seek review before HHS’s Departmental Appeals Board (“DAB”). *Id.* at § 1005.21. Then, ultimately, the affected party may seek judicial review. 42 U.S.C. §§ 405(g), 1320a-7(f).

## **B. Relevant Procedural History**

### **1. Administrative Exclusion Proceedings**

In a May 27, 2021 letter, HHS-OIG notified Dr. Baxter that HHS-OIG proposed to exclude him from participation in federal health programs pursuant to 42 U.S.C. § 1320a-7(a) “[a]s a result of [his] conviction in the United States District Court, Western District of Virginia.” AR 779 (May 27, 2021 Notice Letter).<sup>6</sup> The notice advised Dr. Baxter that he had 90 days to submit a response (including any information and supporting documentation) to the proposed exclusion. *Id.* On

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<sup>6</sup> HHS-OIG withdrew an initial notice of exclusion dated March 31, 2021, after Dr. Baxter initiated a legal action in federal district court alleging that the initial notice violated his procedural due process rights. *See* AR 024 n.8 (DAB Final Decision); *see also* AR 454 ¶ 15 (Compl., *Baxter v. Becerra, et al.*, No. 1:21-cv-451 (E.D. Va. Apr. 13, 2021), ECF No. 1). Under a settlement agreement with Dr. Baxter, HHS-OIG agreed that Dr. Baxter should be allowed ninety days to respond to any future notice. Pl.’s Mem. Supp. 9, ECF No. 23.

August 30, 2021, Dr. Baxter submitted his 22-page response. AR 470–91 (Aug. 30, 2021 Response Letter). HHS-OIG “considered the information furnished” by Dr. Baxter and on September 30, 2021, issued a notice of exclusion notifying Dr. Baxter that effective 20 days later, he would be excluded from Medicare, Medicaid, and all federal health care programs for five years pursuant to § 1320a-7(a)(1) due to his conviction “of a criminal offense related to the delivery of an item or service under Medicare or a State health care program.” AR 535 (September 30, 2021 Exclusion Letter).

Dr. Baxter requested review by an ALJ. Neither party proposed any witnesses and both parties indicated that a hearing was not necessary to the resolution of the matter. AR 002 (ALJ Decision). The ALJ affirmed the Inspector General’s exclusion determination, concluding that Dr. Baxter’s conviction was related to the delivery of a health care item or service under the Medicaid program, and thus he was subject to a mandatory five-year exclusion from federal healthcare programs. AR 001–17.

Dr. Baxter appealed the ALJ’s decision to the DAB, which affirmed, again finding that Dr. Baxter had been convicted of a criminal offense related to the delivery of an item or service under a state health care program, triggering the imposition of a five-year mandatory exclusion. AR 018–50 (DAB Decision).

## 2. Federal Court Action

On November 22, 2022, Dr. Baxter commenced this action in the Alexandria Division of this district. *See* Compl. ¶ 7, ECF No. 1. The case was transferred to the Richmond Division and assigned to the undersigned on February 2, 2022. ECF No. 15. Defendants filed their Answer four days later. ECF No. 17.

On March 8, 2023, Dr. Baxter filed his Motion for Summary Judgment and a Memorandum in Support. *See* ECF Nos. 22, 23. On March 29, 2023, the Defendants filed their Motion for Summary Judgment (also serving as their opposition to Dr. Baxter’s Motion) and their accompanying memorandum. *See* ECF Nos. 24, 25. Dr. Baxter filed his Response to the Defendants’ motion on April 19, 2023. *See* ECF No. 26. The Defendants filed their Reply on May 3, 2023. *See* ECF No. 27. This opinion follows.

### III. DISCUSSION

The question presented here is whether the Secretary reversibly erred in subjecting Plaintiff to mandatory exclusion from federal healthcare programs. Plaintiff argues that the answer is “yes” and offers three reasons why: (1) the Secretary misapplied the relevant statutory provision, 42 U.S.C. § 1320a-7(a)(1); (2) there was no sufficient factual basis for the Secretary to find that Plaintiff was excludable under § 1320a-7(a)(1); and (3) the Secretary’s exclusion of Plaintiff pursuant to § 1320a-7(a)(1) constitutes an arbitrary and capricious departure from past agency practice. *See, e.g.*, Pl.’s Mem. Supp., ECF No. 23. On each score, the Court disagrees.

#### A. The Secretary Correctly Interpreted and Applied 42 U.S.C. § 1320a-7(a)(1)

The Court first considers whether the Secretary misinterpreted and misapplied 42 U.S.C. § 1320a-7(a)(1). The Court “begin[s] with the text” of § 1320a-7(a)(1). *Facebook, Inc. v. Duguid*, 592 U.S. 395, 402 (2021); *see Williams v. Carvajal*, 63 F.4th 279, 285 (4th Cir. 2023) (“As always, an issue of statutory interpretation begins with the text.”). That section provides:

##### (a) Mandatory exclusion

The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a-7b(f) of this title):

##### (1) Conviction of program-related crimes

Any individual or entity that has been convicted of a criminal offense related

to the delivery of an item or service under [Medicare] or under any State health care program[, i.e., Medicaid].

42 U.S.C. § 1320a-7(a)(1).

The Secretary interpreted this language to encompass Plaintiff’s misbranding offense. *E.g.*, AR 018–50 (DAB Decision). Plaintiff argues that the Secretary’s interpretation was wrong and that the Secretary, in fact, does not have the statutory authority to subject Plaintiff to mandatory exclusion. *See, e.g.*, Pl.’s Mem. Supp. 13–14. Plaintiff forwards three interweaving interpretive arguments. First, Plaintiff argues that the major questions doctrine applies to the Secretary’s interpretation, that the Court must find “clear congressional authorization” for the Secretary’s exclusion decision to stand, and that such a clear statement from Congress is lacking here. *Id.* at 14–17. Second, Plaintiff argues that the Secretary unlawfully utilized a circumstance-specific approach to determining whether Plaintiff’s crime was “related to the delivery of an item or service under” a federal or state health care program. *Id.* at 17–20. Plaintiff insists that “related to” in § 1320a-7(a)(1) requires a categorical approach and, under that rubric, Plaintiff’s crime does not trigger mandatory exclusion. *Id.* at 20. Lastly, Plaintiff contends that, even utilizing the circumstance-specific approach, his conviction qualifies for permissive exclusion and thus mandatory exclusion is inapplicable. *Id.* at 20–23.

The Court finds each of Plaintiff’s arguments unavailing and finds that the Secretary properly interpreted 42 U.S.C. § 1320a-7(a)(1) in the challenged respects.<sup>7</sup>

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<sup>7</sup> Because the Court finds no ambiguity in 42 U.S.C. § 1320a-7(a)(1) on any of the presented questions and instead finds that the “traditional tools of statutory construction” all show that the Secretary’s reading in this case is correct, the Court “give[s] effect to the unambiguously expressed intent of Congress” and does not rely on *Chevron* deference in deciding this matter. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43, 843 n.9 (1984).

### 1. The Major Questions Doctrine Does Not Apply

The first issue is whether the major questions doctrine’s clear statement rule applies and undermines the Secretary’s interpretation. The Court concludes that it does not.

The major questions doctrine teaches that “there are ‘extraordinary cases’ . . . in which the ‘history and the breadth of the authority that [the agency] has asserted,’ and the ‘economic and political significance’ of that assertion, provide a ‘reason to hesitate before concluding that Congress’ meant to confer such authority.” *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000)). When an agency reads into “ambiguous statutory text,” “modest words,” “vague terms,” or “subtle device[s]” to assert “extravagant statutory power over the national economy” or other “highly consequential power beyond what Congress could reasonably be understood to have granted,” courts must greet that assertion with “skepticism.” *Id.* at 723–24. The same goes when “an agency claims to discover in a long-extant statute an unheralded power” that “would bring about an enormous and transformative expansion in [the agency]’s regulatory authority without clear congressional authorization.” *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014).

According to Plaintiff, the major questions doctrine applies to the Secretary’s interpretation of 42 U.S.C. § 1320a-7(a)(1) with respect to Plaintiff’s mandatory exclusion because the interpretation “implicates a substantial constitutional question” concerning Plaintiff’s due process rights under the Fifth Amendment,<sup>8</sup> and the implications of the Secretary’s reading counsel caution because such a reading would permit the Secretary to “subject virtually every instance of misbranding to mandatory exclusion.” Pl.’s Mem. Supp. 14, 16–17. The Secretary argues that

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<sup>8</sup> “No person shall . . . be deprived of life, liberty, or property, without due process of law . . . .” U.S. Const. amend. V.

Plaintiff's allegations do not make this the sort of "extraordinary" case where the doctrine applies. Defs.' Mem. Supp. 24, ECF No. 25. Moreover, the Secretary argues that Plaintiff does not even allege any viable due process issue. *Id.* The Court agrees with the Secretary.

*a. Plaintiff Fails to Allege Any Vast Economic or Political Significance to the Secretary's Interpretation*

Plaintiff completely fails to allege the primary indicators of an "extraordinary" major questions doctrine case. Plaintiff never explicitly asserts that the Secretary's reading of § 1320a-7(a)(1) carries any vast economic or political significance. *See generally* Pl.'s Mem. Supp.; Pl.'s Resp., ECF No. 26. Plaintiff's argument that the Secretary's reading would require mandatory exclusion of nearly every misbranding offense does not rise to the necessary level of significance. Even if such a consequence was guaranteed, this does not constitute "highly consequential power" in the national political or economic sense. *See West Virginia v. EPA*, 597 U.S. at 724. Likewise, Plaintiff's generalized attempt to link his adjudication to federally funded health care programs at large, *see* Pl.'s Mem. Supp. 15; Pl.'s Resp. 5, does not make his exclusion a major question. The fact that federally funded health care programs "touch[] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 587 U.S. ----, 139 S. Ct. 1804, 1808 (2019), *quoted in* Pl.'s Resp. 5, does not turn the Secretary's exclusion of a person from federal health programs into an assertion by the Secretary of "extravagant statutory power over the national economy" or the national political landscape, *see West Virginia v. EPA*, 597 U.S. at 724.

In that sense, there is no dispute that this is not a case about whether the Secretary is alleged to have dusted off the cobwebs of § 1320a-7(a)(1) to allow him to undertake wholly new regulatory, rule-making powers impacting far-reaching corners of the economy. This case presents a question of whether the Secretary properly applied his exclusion power—a power indisputably and clearly vested by Congress in the Secretary, a power that the Secretary is *required* by Congress

to exercise in certain circumstances, and a power that the Secretary “has exercised for *decades*,” Defs.’ Mem. Supp. 24 (emphasis in original)—with respect to a single individual.

*b. Plaintiff Establishes No Due Process Problem*

That leaves Plaintiff with his argument that the Secretary’s interpretation could raise due process concerns and that “an agency’s statutory interpretation which ‘implicates a substantial constitutional question’ is ‘of major significance’” and triggers the major questions doctrine. Pl.’s Resp. 5 (quoting *Merck & Co. v. U.S. Dep’t of Health & Hum. Servs.*, 962 F.3d 531, 540–41 (D.C. Cir. 2020)). Assuming Plaintiff is correct that a serious constitutional concern could trigger the major questions doctrine on its own,<sup>9</sup> and further assuming that a due process right were such a constitutional concern, Plaintiff has failed to identify any “substantial constitutional *question*,” *Merck & Co.*, 962 F.3d at 540 (emphasis added), created by the Secretary’s reading here. Plaintiff’s vague due process plea<sup>10</sup> falls far short of posing any difficult due process question for the Court, let alone alleging any due process *violation*.

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<sup>9</sup> Plaintiff points the Court to no case invoking the major questions doctrine where the doctrine’s proponent does not allege that the challenged statutory interpretation has any wide-ranging economic or headline-grabbing political ramifications. Plaintiff only cites one case to support his position that “a substantial constitutional question” alone could support applying the doctrine: *Merck & Co. v. U.S. Dep’t of Health & Hum. Servs.*, 962 F.3d 531. See Pl.’s Mem. Supp. 14, 16; Pl.’s Resp. 5. But the D.C. Circuit in *Merck & Co.* did not apply the major questions doctrine solely because of a serious constitutional difficulty in a proposed interpretation. Rather, the court in *Merck & Co.* focused chiefly on the fact that the “sweeping nature and scope of the authority claimed” by the agency (HHS) could have “major economic or political significance.” 962 F.3d at 540 (quoting *Loving v. IRS*, 742 F.3d 1013, 1021 (D.C. Cir. 2014); and citing *Util. Air Regul. Grp.*, 573 U.S. at 324). Specifically, the *Merck & Co.* panel noted that HHS’s construction of the statute at issue in that case “would seem to give it unbridled power to promulgate any regulation with respect to drug manufacturers that would have the arguable effect of driving down drug prices—or even healthcare costs generally,” which, to the panel, suggested “a staggering delegation of power, far removed from ordinary administration.” *Id.* The “substantial constitutional question” there—a First Amendment concern regarding the regulation of “the public speech of companies”—was a secondary issue considered in tandem with the primary socioeconomic concerns. *Id.*

<sup>10</sup> In his summary judgment motion, Plaintiff solely discusses due process in the context of his statutory interpretation arguments. See generally Pl.’s Mem. Supp. He never frames his arguments as part of a standalone due process claim. See generally *id.*; Pl.’s Resp. This is particularly puzzling given that Plaintiff raised the due process violation on its own in Count III of his Complaint. Compl. ¶¶ 80–83.



Due process rights—whether substantive or procedural—are triggered only by a claim to a cognizable life, liberty, or property interest. *See, e.g.*, U.S. Const. amend. V; *Kerr v. Marshall Univ. Bd. of Governors*, 824 F.3d 62, 80 (4th Cir. 2016). But the deprivation by state action of a constitutionally protected interest in life, liberty, or property is not *in and of itself* unconstitutional. *See, e.g., Kerr*, 824 F.3d at 80. Rather, a constitutional violation only occurs when there is a “deprivation of such an interest *without due process of law*,” in the case of procedural due process claims, *id.* (emphasis in original) (quoting *Zinerman v. Burch*, 494 U.S. 113, 125 (1990)), or the governmental act is “fatally arbitrary” to a constitutional degree, in the case of substantive due process claims, *Hawkins v. Freeman*, 195 F.3d 732, 738 (4th Cir. 1999) (quoting *Cnty. of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998)).

Plaintiff proffers two due process interests implicated by his exclusion: (1) a property interest in his continued participation in the Medicaid program;<sup>11</sup> and (2) a liberty interest in his ability to pursue his career as a medical professional. *See* Pl.’s Mem. Supp. 14–15; Pl.’s Reply 3–4. Binding Fourth Circuit precedent confirms the former as a cognizable property interest. *See Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986) (Butzner, J.) (“[The] expectation of continued participation in the [M]edicare program is a property interest protected by the due process clause of the fifth amendment.”).<sup>12</sup> But the latter, Plaintiff’s purported interest in pursuing his occupation of choice, fares differently. The Supreme Court has stated that there is “some generalized due process right to choose one’s field of private employment.” *Conn v. Gabbert*, 526 U.S. 286, 291–92 (1999). But “all cases recognizing such a right have ‘deal[t] with a *complete prohibition* on the

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<sup>11</sup> Plaintiff did not identify this interest in his Complaint. *See* Compl. ¶¶ 80–83.

<sup>12</sup> In a footnote, the Secretary questions whether *Ram* was correctly decided, citing decisions of other federal courts of appeals declining to recognize such an interest. *See* Defs.’ Mem. Supp. 25 n.8. But Plaintiff accurately notes (and the Secretary necessarily concedes) that that “is not for this Court to decide.” Pl.’s Resp. 3; *see also* Defs.’ Mem. Supp. 25 n.8 (“Defendants acknowledge that [*Ram*] governs whether Dr. Baxter has a property right in his continued participation in Medicare.”).

right to engage in a calling, and not [a] sort of brief interruption.” *Guzman v. Shewry*, 552 F.3d 941, 954 (9th Cir. 2009) (alterations and emphasis in original) (quoting *Conn*, 526 U.S. at 292); accord *Aquino v. City of Charlotte*, 2022 WL 2334985, at \*3 (W.D.N.C. June 28, 2022) (citing *Conn*, 526 U.S. at 291–92). In that sense, Plaintiff’s attempts to establish his exclusion as implicating a cognizable liberty interest fails twice over. Strictly speaking, Plaintiff’s temporary exclusion from the Medicare program does not *completely* exclude him from the entirety of the medical profession or from working in the pharmaceutical industry, just jobs that involve federal funding.<sup>13</sup> Moreover, this exclusion is temporary—lifting after five years—so it is more a “brief interruption” than a “complete prohibition.”<sup>14</sup> Plaintiff has thus not persuaded the Court that his temporary exclusion deprives him of a protected liberty interest in pursuing the occupation of his choice. Only Plaintiff’s property interest is cognizable.

Plaintiff’s position is that simply alleging the implication of his “indisputable property interest under binding Fourth Circuit precedent suffices to bring major questions . . . principles into play here.” Pl.’s Resp. 4. That cannot be so. Merely identifying a cognizable interest for due process purposes does not establish any “substantial” “*question*” about the constitutionality of governmental action. *Merck & Co.*, 962 F.3d at 540 (emphasis added); *see, e.g., Kerr*, 824 F.3d at 80 (“[D]eprivation . . . of a constitutionally protected interest in life, liberty, or property is not in itself unconstitutional[.]”). Whether there is any serious *question* of constitutionality in this case can only be determined by answering the question of what the Due Process Clause *requires* with respect to a deprivation of that cognizable interest—i.e., exactly what, if any, additional

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<sup>13</sup> In fact, Plaintiff has not even pointed the Court to any specific information or evidence to establish that he has been foreclosed from practicing his chosen profession. *See* Defs.’ Mem. Supp. 25–26; Defs.’ Reply 9 n.5, ECF No. 27.

<sup>14</sup> Plaintiff argues that because he “is already in his sixties,” “a five-year exclusion likely ends his career,” making this exclusion more of “a complete prohibition” than “a brief interruption.” Pl.’s Resp. 4. But Plaintiff’s age does not change the fact that Plaintiff’s exclusion is not a permanent, complete prohibition.

process is due (procedural) or what justification is required (substantive). There can be no “substantial constitutional question,” *Merck & Co.*, 962 F.3d at 540, unless the process accorded or justification provided is deficient (or, at the very least, arguably so).

The method of assessing whether there is a due process deficiency differs depending on whether the due process challenge is procedural or substantive. *See, e.g., Kerr*, 824 F.3d at 80. Here, Plaintiff never specifically states whether his is a substantive due process or a procedural due process argument. Defs.’ Reply 9, ECF No. 27 (noting the same). In either event, there is no question: Plaintiff does not demonstrate any constitutional violation, problem, or doubt.

As to procedural due process, the Court finds no deficiency in the process accorded to Plaintiff. By the time the Secretary’s exclusion determination was affirmed by the DAB, Plaintiff enjoyed the full panoply of procedural safeguards in: (1) the antecedent federal criminal prosecution against him; (2) his appeal of the Secretary’s suspension letter to the ALJ; and (3) his appeal of the ALJ’s decision to the DAB. *See, e.g., AR 001–17* (ALJ Decision); *AR 018–50* (DAB Decision); *see also* Compl. ¶ 48. Additionally, Plaintiff was provided an opportunity to be heard *before* the Secretary issued his operative suspension letter in the form of an opportunity to file a written response. *See, e.g., AR 470–91* (Aug. 30, 2021 Response Letter); *see also* Compl. ¶ 46. The Court finds this process constitutionally adequate. *See, e.g., Ram*, 792 F.2d at 447 (holding, in procedural due process challenge to deprivation of continued participation in the Medicare program, that criminal proceedings afforded plaintiff “ample process to assert his innocence” and this interest “d[id] not merit the protection of a presuspension hearing”);<sup>15</sup> *Erickson v. U.S. ex rel. Dep’t of Health & Hum. Servs.*, 67 F.3d 858, 863 (9th Cir. 1995) (holding that plaintiffs “received

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<sup>15</sup> The *Ram* court did find that the plaintiff was “entitled . . . to a prompt postsuspension hearing.” 792 F.2d at 447. Plaintiff here was afforded at least one opportunity for a hearing after the Secretary’s suspension determination but “indicated that a hearing was not necessary to resolve this matter.” AR 002 (ALJ Decision).

adequate due process” with respect to their mandatory exclusion because plaintiffs’ criminal convictions, though on appeal, carried sufficient procedural protections and, “because 42 U.S.C. § 1320a–7(a)(1) mandates exclusion once a conviction occurs, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., [was] not necessary before excluding a physician convicted” of a covered crime (internal quotation marks omitted)).

Likewise, the Court finds no substantive due process violation. If Plaintiff is challenging executive action, *see* Pl.’s Mem. Supp. 15 (suggesting that the due process violation comes from “[t]he Secretary’s unwarranted exclusion” of Plaintiff), such a challenge fails. Plaintiff makes no argument that the Secretary’s exclusion of him was “so egregious, so outrageous, that it may fairly be said to shock the contemporary conscience.” *Hawkins*, 195 F.3d at 738 (quoting *Lewis*, 523 U.S. at 847 n.8). The Secretary interpreted a statute as part of his duties, concluded that the mandatory exclusion provision applied, and thus had to exclude Plaintiff. This cannot possibly be understood as conscience-shocking.

If Plaintiff is challenging § 1320a-7(a) and its mandatory nature as a legislative enactment, *see* Pl.’s Mem. Supp. 17 (suggesting § 1320a-7(a) “infring[es] on due process rights by eliminating the Secretary’s ability to consider mitigating circumstances in determining whether exclusion is appropriate”), or the fact it can be triggered by a strict liability offense, *see* Pl.’s Reply 4 (citing *Morissette v. United States*, 342 U.S. 246, 256 (1952)) (“Because the penalty the Secretary would impose based on Dr. Baxter’s strict liability conviction is so far reaching, it is disproportionate to his offense.”), such a challenge must also be rejected. Unless an asserted interest is a fundamental one, a statute is subject only to rational basis review. *See, e.g., McArthur v. Brabrand*, 610 F. Supp. 3d 822, 845 (E.D. Va. 2022). Rational basis review affords a statute a “strong presumption of validity” and requires that the statute be upheld if it is “rationally related to a legitimate

governmental interest.” *Thomasson v. Perry*, 80 F.3d 915, 928 (4th Cir. 1996) (en banc). The rational basis standard “puts the burden on plaintiffs ‘to negative every conceivable basis which might support’” the statute. *McArthur*, 610 F. Supp. 3d at 840 (quoting *Thomasson*, 80 F.3d at 928).

Section 1320a-7(a) need only pass rational basis muster. Plaintiff has not demonstrated that his sole implicated interest—a property interest in continued participation in Medicare or Medicaid—is a fundamental right. In fact, Plaintiff never urges the Court to engage in strict scrutiny review, further underscoring the incomplete nature of Plaintiff’s due process argument. In his opening brief, Plaintiff makes a passing, conclusory mention to “his fundamental rights” being at issue (a suggestion never made in his Complaint nor repeated in his response brief). Pl.’s Mem. Supp. 15. But when the Fourth Circuit recognized a continued-participation property interest as cognizable in *Ram*, it never described it as “fundamental.” *See generally* 792 F.2d at 445–47. Neither did do so in the sole case *Ram* cited on this point, *Bowens v. North Carolina Department of Human Resources*, 710 F.2d 1015 (4th Cir. 1983). Common sense confirms this conclusion—one could not seriously suggest (and in fact, Plaintiff never does suggest) that one’s continued participation in Medicare or Medicaid is the sort of right so “deeply rooted in this Nation’s history and tradition” such that “neither liberty nor justice would exist if [it] were sacrificed.” *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997).

Applying rational basis review, any intimation of a substantive due process violation must be rejected. Plaintiff never specifically opines as to why Congress’s decision to make exclusion in certain circumstances mandatory or the fact that exclusion could theoretically come about due to a strict liability misdemeanor offense is irrational. In so failing, Plaintiff gives the Court no basis to disagree with the persuasive reasoning of other courts finding no substantive due process

problem with § 1320a-7(a)'s mandatory nature generally. *See Harkonen v. Sebelius*, 2013 WL 5734918, at \*16 (N.D. Cal. Oct. 22, 2013) (citing *Friedman*, 686 F.3d at 820, 824; citing *Morgan v. Sebelius*, 694 F.3d 535, 538 (4th Cir. 2012) (per curiam); and citing *Manocchio v. Kusserow*, 961 F.2d 1539, 1541–42 (11th Cir. 1992))) (“[E]xclusion [under § 1320a-7(a)] is rationally related to the government’s interests in deterring fraud in the delivery of health care and health care items and services, and in protecting federal health care programs and their beneficiaries from individuals who have behaved in an untrustworthy manner.”). Nor does to the Court find a substantive due process problem with the fact that exclusion from federal healthcare programs can be triggered by a strict liability misdemeanor misbranding offense. *See Friedman*, 686 F.3d at 824 (confronting a *Morissette*-based strict liability argument and concluding that exclusion “on the basis of [a] conviction for a strict liability offense” does not “raise[] any significant concern with due process”).<sup>16</sup>

The Court thus finds no substantial question of validity under the Fifth Amendment’s Due Process Clause.<sup>17</sup>

### *c. Summation*

With no alleged sweeping economic or political implications and no serious cognizable constitutional question attached to the Secretary’s interpretation of § 1320a-7(a)(1), the Court concludes with ease that the major questions doctrine does not apply in this case. Thus, the

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<sup>16</sup> Plaintiff insists that *Friedman* is inapposite in the due process analysis because that case dealt with the permissive exclusion provision, whereas this case deals with the mandatory exclusion provision. But the question the Court relies on *Friedman* to answer here is whether “the penalty the Secretary would impose based on [a] strict liability conviction” comports with substantive notions of due process. Pl.’s Resp. 4. Since the ultimate penalty is the same under either the permissive or mandatory provision—exclusion—the Court finds *Friedman* fully applicable in this specific respect.

<sup>17</sup> For the first time in his response to the Government’s summary judgment motion, Plaintiff squarely raises a distinct constitutional avoidance argument, arguing that this canon also applies and also requires a clear statement. Pl.’s Resp. 2, 5. But because the Court concludes that the Secretary’s reading raises no constitutional problem, the canon against constitutional avoidance is inapplicable. There is nothing to avoid.

Secretary's reading will be upheld so long as it merely comports with § 1320a-7(a)(1)'s plain text—no “clear statement” is required.

2. The Secretary's Circumstance-Specific Approach Comports with § 1320a-7(a)(1)'s Plain Text

The Court turns to whether the Secretary properly interpreted § 1320a-7(a)(1) when he concluded that Plaintiff's misbranding conviction was of “a criminal offense related to the delivery of an item or service under . . . any State health care program,” i.e., Medicaid. 42 U.S.C. § 1320a-7(a)(1).

The dispute here is over § 1320a-7(a)(1)'s “related to” language. The Secretary has read this phrase to contemplate a “circumstance-specific approach,” *see, e.g.*, AR 014 (ALJ Decision), one that looks to “the facts upon which the conviction was predicated” and “requires only that a common-sense nexus exists between the offense and the delivery of a health care item or service under the [federal or] state healthcare program,” AR 032 (DAB Decision) (quoting *Summit S. Shah, M.D.*, DAB No. 2836, 2017 WL 7734858, at \*6–7 (H.H.S. Dec. 18, 2017)); *see also id.* at 032 n.15 (collecting supporting Supreme Court cases). Plaintiff disagrees with the Secretary's circumstance-specific approach, instead arguing that “related to” in § 1320a-7(a)(1) requires a categorical, element-focused approach and “includes only a crime that *by its terms* involved the delivery of an item or service under Medicare or Medicaid.” Pl.'s Mem. Supp. 20 (emphasis added).

The categorical approach “is not a default rule of statutory construction.” *United States v. Pena*, 952 F.3d 503, 508 n.4 (4th Cir. 2020). Courts apply it “when compelled to do so by the text of the applicable statute.” *Id.* When a statute's text “refers expressly or implicitly to conduct,” *id.*, that is, “to the specific way in which an offender committed the crime on a specific occasion,”

rather than to the generic crime,” *United States v. Price*, 777 F.3d 700, 705 (4th Cir. 2015) (quoting *Nijhawan v. Holder*, 557 U.S. 29, 34 (2009)), the circumstance-specific approach applies.

Unfortunately for Plaintiff, a functionally identical argument to the “relat[e] to” argument he raises here has failed elsewhere; for functionally identical reasons, his fails here. In *Friedman v. Sebelius*, the D.C. Circuit was posed with the question of whether “relating to” in “misdemeanor relating to fraud” in 42 U.S.C. § 1320a-7(b)(1)(A) contemplated a categorical or circumstance-specific approach. 686 F.3d at 818–19. The plaintiffs (that is, the excludees) there argued for the former, but the court rejected this “crabbed and formalistic interpretation.” *Id.* at 820. The court recognized that the ordinary meaning of “relating to” is “broad”—“to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.” *Id.* (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992)). Citing Supreme Court precedents further underscoring the “deliberately expansive” and “capacious” nature of this language, *Friedman* found that this phrase refers to specific circumstances of conduct and accordingly held that “a misdemeanor ‘relat[es] to’ fraud” if the misdemeanor “has a factual ‘connection with’ fraud.” *Id.* (alteration in original).

*Freidman*’s reading dictates the interpretive result here. Though *Friedman* construed § 1320a-7(b)(1)(A), a permissive exclusion provision, both §§ 1320a-7(b)(1)(A) and 1320a-7(a)(1) use the operative phrase “relat[e] to.” See § 1320a-7(b)(1)(A) (“relating to”); § 1320a-7(a)(1) (“related to”); see also *Friedman*, 686 F.3d at 822 (“related to” and “relating to” are “functionally identical”). It is a “standard principle of statutory construction . . . that identical words and phrases within the same statute should normally be given the same meaning.” *Watson v. United States*, 552 U.S. 74, 81 (2007). Plaintiff never expressly argues that *Friedman* was wrongly decided, and his attempts to reconcile his position with *Friedman* are wholly unresponsive



to the key textual “relat[e] to” link. Plaintiff contends that “there are plausible grounds for the agency to consider the underlying facts in determining whether to impose a punishment” in the case of permissive exclusion, because the Secretary could choose to not impose exclusion at all. Pl.’s Resp. 9. But this terse argument conspicuously lacks any reference to the text of either § 1320a-7(b)(1)(A) or § 1320a-7(a)(1).

With no textual basis to depart from *Friedman*’s “relat[e] to” analysis and no specific genus of crime enumerated in § 1320a-7(a)(1), the Court accords “related to” in § 1320a-7(a)(1) a consistent meaning as referencing a factual relationship.<sup>18</sup> Thus, a “criminal offense relate[s] to the delivery of an item or service under [Medicare] or [Medicaid]” under § 1320a-7(a)(1) when the crime has a factual connection with the delivery of an item or service under Medicare or Medicaid.

Plaintiff’s other arguments to the contrary are all unavailing. Plaintiff points to a footnote from one out-of-circuit district court case to argue that a circumstance-specific, “common sense” nexus test is improper. Pl.’s Mem. Supp. 18–19 (discussing *Kabins v. Sebelius*, 2012 WL 4498295, at \*3 n.1 (D. Nev. Sept. 28, 2012)). But the observations in that footnote are accompanied by no citations to any caselaw, are based on different facts, and have been minimized by another district court in that circuit as “dicta at best.” *Harkonen*, 2013 WL 5734918, at \*8.

Plaintiff next invokes a provision of the Immigration and Naturalization Act, 8 U.S.C. § 1227(a)(2)(B)(i), to assert that Congress’s use of “relat[e] to” always mandates a categorical approach. Pl.’s Mem. Supp. 19–20. But Plaintiff fails to account for context, “err[ing] by focusing

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<sup>18</sup> Hammering home the consistency point, another district court has observed that “relat[e] to” “appears in nearly every provision of § 1320a-7,” and “the phrase . . . is used throughout § 1320a-7 under circumstances where the only logical construction of the phrase requires assessment of factual connectedness.” *Bohner v. Burwell*, 2016 WL 8716339, at \*6 (E.D. Pa. Dec. 2, 2016); see also *Friedman*, 686 F.3d at 821 (pointing to other sections where “the phrase ‘relating to’ denotes a factual relationship”).

narrowly upon the phrase ‘relat[e] to’ in” § 1227(a)(2)(B)(i) and “paying no heed to the words connected by that phrase.” *Friedman*, 686 F.3d at 823. Section 1227(a)(2)(B)(i) authorizes the deportation of an “[a]ny alien . . . convicted of a violation of . . . any law or regulation of a State, the United States, or a foreign country relating to a controlled substance (as defined in section 802 of Title 21).” 8 U.S.C. § 1227(a)(2)(B)(i) (emphasis added). So, in § 1227(a)(2)(B)(i), “relating to” modifies “law or regulation,” linking it to federally “controlled substance[s].” “An assessment of a particular law or regulation necessitates an assessment of the elements it comprises.” *Bohner v. Burwell*, 2016 WL 8716339, at \*8 (E.D. Pa. Dec. 2, 2016) (citing *Mellouli v. Lynch*, 575 U.S. 798, 813 (2015)); *see also Friedman*, 686 F.3d at 823 (“A ‘law or regulation’ . . . cannot refer to the facts of a particular incident.”). In contrast, “related to” in § 1320(a)-7(a)(1) links “criminal offense” to “delivery of an item or service under” Medicare or Medicaid. A “criminal offense” is just a “crime,”<sup>19</sup> i.e., “[a]n *act* that the law makes punishable.” *Crime*, BLACK’S LAW DICTIONARY (11th ed. 2019) (emphasis added); *see also Offense*, OXFORD ENGLISH DICTIONARY (accessed Jan. 15, 2024), [https://www.oed.com/dictionary/offence\\_n](https://www.oed.com/dictionary/offence_n) [<https://perma.cc/VG7M-9RY8>] (“2.b. *Law*. An illegal *act or omission*; a punishable crime.” (emphasis added)). Thus, § 1320(a)-7(a)(1)’s focus is on characterizing wrongful *acts*, while § 1227(a)(2)(B)(i)’s focus is on comparing laws. Statutory context thus justifies the differing results that “relat[e] to” yields.

Plaintiff goes broader in his response, insisting that “the Supreme Court has shown extreme skepticism in response to government claims that it may look beyond the elements of a prior conviction in deciding whether to impose subsequent consequences.” Pl.’s Resp. 8. But Plaintiff cites inapposite cases. Plaintiff first cites *United States v. Davis*, 588 U.S. ----, 139 S. Ct. 2319

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<sup>19</sup> “The terms ‘crime,’ ‘offense,’ and ‘criminal offense’ are all said to be synonymous, and ordinarily used interchangeably.” *Offense*, BLACK’S LAW DICTIONARY (11th ed. 2019) (quoting 22 C.J.S. Criminal Law § 3 (1989)).

(2019) and *Sessions v. Dimaya*, 584 U.S. ----, 138 S. Ct. 1204 (2018), for the proposition that “the Supreme Court has gone so far as to hold statutes invalid that call for [a circumstance-specific] inquiry.” Pl.’s Resp. 8. *Davis* and *Dimaya* are off-point for two reasons. First, they are cases where the Supreme Court struck down certain statutes as vague, and Plaintiff brings no vagueness challenge to § 1320a-7(a)(1). But worse, they are cases where the Court found the statutory provisions were vague because they required *categorical* approaches—not circumstance-specific ones. *See Davis*, 139 S. Ct. 2319, 2326–27 (recounting that with respect to the provision at issue in *Dimaya*, “our precedent . . . required courts to use the categorical approach,” and noting that for the provision at issue in *Davis*, “[f]or years, almost everyone understood [it] to require exactly the same categorical approach that this Court found problematic” in *Dimaya*).

Plaintiff then cites *United States v. Taylor*, 596 U.S. 845 (2022), and *Mathis v. United States*, 579 U.S. 500 (2016), to aver that the Supreme Court “has generally approved of interpretations that call for the government to consider, when determining collateral consequences for a prior conviction, only conduct necessary to establish the commission of the prior crime.” Pl.’s Resp. 8–9. But *Taylor* and *Mathis* do not stand for the proposition that categorical approaches are favored; those are simply cases where there was no dispute that a categorical approach applied given the specific statutory context presented. *See Taylor*, 596 U.S. at 850 (parties “agree[d]” that Court “must apply a ‘categorical approach’”); *Mathis*, 579 U.S. at 503–04 (no dispute that categorical approach applied). And in any event, the language of the specific statutory phrases considered in *Taylor* and *Mathis*—both, among other things, lacking the key “relat[e] to” phrase—have no application to § 1320a-7(a)(1). *Compare* 42 U.S.C. § 1320a-7(a)(1) (crime is a “program-related crime[]” if it is “related to the delivery of an item or service under [Medicare] or under [Medicaid]”), *with* 18 U.S.C. § 924(c)(3)(A) (crime is a “crime of violence” if it “has as an element

the use . . . of physical force” (emphasis added)), *construed in Taylor*, 596 U.S. 845, and 18 U.S.C. § 924(e)(2)(B)(ii) (felony is a “violent felony” if it “is burglary, arson, or extortion”), *construed in Mathis*, 579 U.S. 500.

Plaintiff says a lot, but he fails to identify how the text of § 1320a-7(a)(1) contemplates a categorical, element-specific approach. Section 1320a-7(a)(1) does not refer to “elements,” nor does it enumerate any generic classification of crime. Plaintiff fails to reckon with *Friedman*’s textual underpinnings and justify a contrary result here in the face of the functionally identical, fact-implying phrase appearing in the same statute. For these reasons, the Court cannot say that the Secretary misapplied 42 U.S.C. § 1320a-7(a)(1) by employing a circumstance-specific approach.

3. The Secretary’s Reading of § 1320a-7(a)(1)’s Text is Appropriate Even if Plaintiff’s Offense Could Also Conceivably Fall into a Permissive Exclusion Category

Plaintiff also raises an alternative, circumstance-specific argument. Plaintiff argues that even if the Secretary’s circumstance-specific approach is proper, under that approach, his offense at most qualifies for permissive exclusion as “a misdemeanor relating to fraud.” Pl.’s Mem. Supp. 20 (quoting 42 U.S.C. § 1320a-7(b)(1)(A)). Plaintiff argues that because mandatory and permissive exclusion are “mutually exclusive,” *id.* at 2, 23 (citing *Travers v. Sullivan*, 801 F. Supp. 394, 404 (E.D. Wash. 1992)), “if [his] conduct is subject to permissive exclusion, then ‘the mandatory provision is inapplicable,’” *id.* at 20 (quoting *Leddy v. Becerra*, 617 F. Supp. 3d 116, 123 (E.D.N.Y. 2022)).

Plaintiff is technically correct that mandatory and permissive exclusion are “mutually exclusive” in the sense that the text of § 1320a-7 does not permit the Secretary to apply both mandatory and permissive exclusion in the same case. But Plaintiff has it backward when he suggests that this “mutual exclusivity” means that if a permissive exclusion provision could

conceivably apply, that automatically nullifies the applicability of an otherwise applicable mandatory exclusion provision. *Travers v. Sullivan*, the case Plaintiff cites for his “mutually exclusive” proposition, explains it well: “An exclusion determination under § 1320a-7 is a two-step process.” *Travers*, 801 F. Supp. at 405, *aff’d sub nom. Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994). First, the Secretary must determine whether the mandatory provision, § 1320a-7(a), applies. *Travers*, 801 F. Supp. at 405. Under § 1320a-7(a), the Secretary “shall exclude” individuals who have been convicted of, *inter alia*, “program-related crimes.” 42 U.S.C. § 1320a-7(a)(1). Thus, “[i]f the prerequisites of this section are met, the Secretary is directed by Congress to exclude that individual, and the issue of permissive exclusion becomes moot.” *Travers*, 801 F. Supp. at 405. The Secretary can proceed to the permissive, discretionary exclusion inquiry “only after the Secretary determines that the individual’s conviction was not for a ‘program-related crime.’” *Id.* So, when one says that mandatory and permissive exclusion are “mutually exclusive” categories, that is simply a reflection of the statutory text which only allows permissive exclusion *if mandatory exclusion does not apply* by the text of those provisions.<sup>20</sup>

The case Plaintiff cites to suggest that permissive exclusion ought to always overcome mandatory exclusion, *Leddy v. Becerra*, does not upset this understanding, nor does it otherwise dictate a finding that § 1320a-7(a)(1) is inapplicable under these particular facts. 617 F. Supp. 3d 116 (E.D.N.Y. 2022). *Leddy* dealt not with someone convicted of a misdemeanor misbranding offense, but rather with a doctor who had been convicted of obstructing a potential Medicare audit. *See* 617 F. Supp. 3d at 118. The *Leddy* court examined § 1320a-7(a)(1)’s mandatory exclusion language first, finding any “reading of [§ 1320a-7(a)(1)] which would apply [t]here, . . . at best,

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<sup>20</sup> Confusingly enough, Plaintiff acknowledges as much in his response brief, admitting that the Secretary “does not have discretion in deciding whether to apply a mandatory exclusion *where a conviction is covered by section [1320a-7](a)(1).*” Pl.’s Resp. 12 (citing *Travers*, 801 F. Supp. at 405) (emphasis in original). Still, the Court soldiers on through the remainder of Plaintiff’s argument.

attenuated,” but ultimately entirely “fail[ing]”—given the specific circumstances alleged by the Secretary there—because “*the subject audit was never conducted.*” *Id.* at 123 (emphasis in original). Only then proceeding to permissive exclusion, the *Leddy* court found permissive exclusion applicable because § 1320a-7 includes a provision that *specifically* calls for permissive exclusion for a conviction “in connection with the interference with or obstruction of any investigation or audit related to the use of funds received, directly or indirectly, from any Federal health care program.” 42 U.S.C. § 1320a-7(b)(2)(ii); *Leddy*, 617 F. Supp. 3d at 123. In light of that express, specific statutory language, the court found any “purported applicability” of mandatory exclusion would be “entirely undermined” in the face of the specific permissive exclusionary provision and the “well-established principle[]” that “the specific governs the general.” *Leddy*, 617 F. Supp. 3d at 123–24.

*Leddy*’s conclusion that the plain text of § 1320a-7(a)(1) did not cover the obstructed audit there obviously has no bearing on whether the plain text of § 1320a-7(a)(1) covers the facts of this misdemeanor misbranding offense. And on the arguments and allegations here,<sup>21</sup> Plaintiff has not convinced the Court that the Secretary’s reading of § 1320a-7(a)(1)<sup>22</sup> constitutes a facially “fail[ing]” or “at best, attenuated” construction of the statute. *See Leddy*, 617 F. Supp. 3d at 123. Far from it. Plaintiff’s crime, as alleged, comfortably qualifies as “program-related” within the meaning of § 1320a-7(a)(1).<sup>23</sup> Since § 1320a-7(a)(1)’s text covers the crime here, that is the end of the matter, and *Leddy* is inapposite.

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<sup>21</sup> Plaintiff argues that the Secretary’s factual findings lack sufficient evidentiary support. That is a distinct argument that the Court considers (and rejects) *infra*.

<sup>22</sup> Again, that reading in this case is that “criminal offense related to the delivery of an item . . . under any State health care program” covers the offense of causing the introduction or delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded through false and misleading statements made directly to MassHealth. *See* AR 023 (DAB Decision) (citing AR 547, ¶ 33 (Information) and AR 549 (Plea Agreement)).

<sup>23</sup> Plaintiff now welcomes *Friedman v. Sebelius*, arguing that that case shows that RCO misdemeanor misbranding offenses are grounds only for permissive exclusion and thus that § 1320a-7(a)(1)’s text cannot cover

But to the extent *Leddy* could be read as standing for the proposition that a specific permissive exclusion provision can cause § 1320a-7(a)(1) to not apply *even when § 1320a-7(a)(1)’s text otherwise covers the conduct at issue*, the Court is not persuaded that this is such a case. For one, unlike the super specific permissive exclusion provision obviously applicable in *Leddy*, Plaintiff asserts merely that § 1320a-7(b) “contains language that is objectively closer to the offense for which [he] was convicted.” Pl.’s Resp. 12. “Objectively closer” is not the same as the uniquely tight specificity presented in *Leddy*. But more fundamentally, Plaintiff’s argument for why “[p]ermissive exclusion more specifically addresses [his] offense” is that permissive exclusion “enacts ‘Congress[’s] intent that an individual may be excluded from the Medicare and Medicaid programs’ for misconduct that ‘had nothing to do with Medicare or Medicaid.’” Pl.’s Mem. Supp. 21 (emphasis omitted) (quoting *Travers*, 801 F. Supp. at 404–05). But the false and misleading statements Plaintiff failed to promptly correct were made *directly to* the representative of a state health care program—i.e., Medicaid. *E.g.*, AR 024 (DAB Decision) (quoting AR 547, ¶ 32 (Information)). So, in this case, there is no basis to say that Plaintiff’s crime “had nothing to do with Medicare or Medicaid.” Pl.’s Mem. Supp. 21 (quoting *Travers*, 801 F. Supp. at 404–05). Plaintiff’s arguments on this point are unpersuasive on all fronts.

In sum, Plaintiff’s view that his offense fits better into permissive exclusion does not render the Secretary’s interpretation of § 1320a-7(a)(1) in this case improper.

## **B. Plaintiff’s Exclusion is Supported by Substantial Evidence**

The Court next considers whether the Secretary’s factual findings are “supported by

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Plaintiff’s crime. *See* Pl.’s Mem. Supp. 21–23. But “[e]ven if *Friedman* stands for the proposition that some misdemeanor misbranding convictions are subject to the permissive exclusion, *Friedman* did not address whether misdemeanor misbranding was subject to mandatory exclusion when HHS determined that it was a ‘program-related crime’ under 42 U.S.C. § 1320a-7(b)(1).” *Parrino v. Price*, 869 F.3d 392, 400 (6th Cir. 2017).

substantial evidence.” 42 U.S.C. § 405(g). The Court concludes that they are.

Substantial evidence “means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consol. Edison Co. of N.Y. v. N.L.R.B.*, 305 U.S. 197, 229 (1938)). It “consists of more than a mere scintilla of evidence but may be somewhat less than a preponderance.” *Hays v. Sullivan*, 907 F.2d 1453, 1456 (4th Cir. 1990) (quoting *Laws v. Celebrezze*, 368 F.2d 640, 642 (4th Cir. 1966)). “In reviewing for substantial evidence, [the Court] do[es] not undertake to reweigh conflicting evidence, make credibility determinations, or substitute [its] judgment for that of the [ALJs].” *Hancock v. Astrue*, 667 F.3d 470, 472 (4th Cir. 2012). “Ultimately, it is the duty of the administrative law judge reviewing a case, and not the responsibility of the courts, to make findings of fact and to resolve conflicts in the evidence.” *Hays*, 907 F.2d at 1456. If substantial evidence supports the Secretary’s decision, then the Secretary’s findings “shall be conclusive.” 42 U.S.C. § 405(g).

Upon review, the Court finds substantial evidence in the record to justify Plaintiff’s exclusion from program participation under 42 U.S.C. § 1320a-7(a)(1) for committing a “criminal offense related to the delivery of an item or service” under a state health care program. 42 U.S.C. § 1320a-7(a)(1). As Plaintiff’s Information makes clear,<sup>24</sup> Suboxone Film was misbranded because of false and misleading statements that Plaintiff’s direct subordinate at RPB (now Indivior) made to MassHealth (the state health care program) about Suboxone Film’s safety. AR

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<sup>24</sup> In his Response, Plaintiff appears to take issue with the DAB’s reliance on the facts established by his conviction. Pl.’s Resp. 17 (“The government feels at liberty to employ any facts referenced within the Information associated with Dr. Baxter’s conviction . . .”). But the Court sees nothing wrong with the DAB’s consideration of this evidence. Plaintiff admitted to the factual allegations in the Information. *See, e.g., id.* Moreover, it is common practice for the Agency, when undertaking the circumstance-specific approach, to consider “‘evidence as to the nature of an offense,’ including the ‘facts upon which the conviction was predicated’” in determining whether the requisite nexus exists under § 1320a-7(a)(1). *Yolanda Hamilton*, DAB No. 3061, 2022 WL 2197302, \*7 (H.H.S. May 2, 2022) (quoting *Shah*, DAB No. 2836, 2017 WL 7734858, \*7).



545–47 (Information). Plaintiff, “as a responsible [RBP] executive, failed to prevent and promptly correct” that misbranding. *Id.* at 547, ¶ 32. There is clearly a nexus between these facts—to which Plaintiff pleaded guilty, admitted, and which are not in dispute here—and the delivery of items, i.e., Suboxone Film, paid for by a state health care program, i.e., MassHealth.<sup>25</sup>

Contrary to Plaintiff’s contentions, the DAB did not err by considering and weighing the testimony of MassHealth’s Pharmacy Director, Dr. Paul Jeffrey, to confirm this nexus—i.e., to find that the misbranding played a role in MassHealth’s decision to expand coverage. As a threshold matter, Plaintiff argues that the DAB erred in relying on Dr. Jeffrey’s testimony in the first instance because Plaintiff “had no opportunity to cross-examine Dr. Jeffrey as is his ‘right[.]’” Pl.’s Mem. Supp. 28 (quoting 42 C.F.R. § 1005.3(a)(6), and citing *Wallace v. Bowen*, 869 F.2d 187, 193–94 (3d Cir. 1989), and *Mase v. Comm’r of Soc. Sec.*, 2022 WL 1184801, at \*3 (D.N.J. Apr. 21, 2022)). The Court disagrees. The operative regulations provided Plaintiff the right to request a hearing, 42 C.F.R. § 1005.2, “[p]resent and cross-examine witnesses,” *id.* § 1005.3(a)(6), and move the ALJ to subpoena any such witness to attend, *id.* § 1005.9(a). Plaintiff chose to do none of this despite the fact, as the DAB found (and Plaintiff never disputes), that Plaintiff was “aware that the [Secretary] intended to rely on the transcript of Dr. Jeffrey’s testimony.” AR 030 (DAB Decision). So, in that sense, Plaintiff *did* have the opportunity to call Dr. Jeffrey and poke holes in his testimony. Even so, there is no intimation from Plaintiff that he was not given “reasonable notice” of the Secretary’s intentions to rely on the testimony. This, at the very least, “strongly implie[s]” waiver of his right to cross-examine Dr. Jeffrey given the circumstances. *See Wallace*, 869 F.2d at 193.

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<sup>25</sup> Plaintiff argues that the DAB “failed entirely to consider alternative—and often more logical—inferences that could be drawn from the facts” in the Information. Pl.’s Resp. 18. But on substantial evidence review, the Court has no occasion to “reweigh . . . evidence . . . or substitute [its] judgment for that of the [DAB].” *Hancock*, 667 F.3d at 472.

In any event, the two cases Plaintiff cites to argue that consideration of this testimony constitutes reversible error, *Wallace* and *Mace*, are distinguishable because both dealt with cross-examination of “post-hearing” witness. See *Wallace*, 869 F.2d at 193–94 (“Waiver of the right to subpoena and cross-examine witnesses concerning *post-hearing evidence* must be clearly expressed or strongly implied from the circumstances.” (emphasis added)); *Mase*, 2022 WL 1184801, at \*3 (“[T]he ALJ must afford the claimant not only the opportunity to comment and present evidence but also an opportunity to cross-examine the authors of any *post-hearing reports* when such cross-examination is necessary to the full presentation of the case . . . .” (emphasis added)). That is a far cry from the situation here—where Dr. Jeffrey’s testimony predated the potential hearing date, Plaintiff was aware that Dr. Jeffrey’s testimony would be used, Plaintiff held tools at his disposal to cross-examine Dr. Jeffrey, and Plaintiff still did not exercise his rights to do so. With *Wallace* and *Mace* inapposite, Plaintiff’s argument that “it was incumbent on [the Secretary] to call Dr. Jeffrey if he intended to rely on his testimony,” Pl.’s Mem. Supp. 28, hangs in the air with no caselaw to support it. Considering all of the circumstances here, the Court is in no position to disagree with the DAB’s conclusion that Plaintiff cannot “render Dr. Jeffrey’s prior testimony inadmissible by declining to examine him.” AR 030 (DAB Decision).

The Court next turns to the substance of Dr. Jeffrey’s testimony. Dr. Jeffrey testified that the correct October 2012 RADARS data regarding the unintended pediatric exposure rates among buprenorphine-only tablets, Suboxone Film, and Suboxone Tablets in Massachusetts “[a]bsolutely” would have mattered to him. AR 690 (Testimony of Dr. Jeffrey at Sent’g Hr’g in *United States v. Thaxter*, 1:20cr24 (W.D. Va. Oct. 22, 2020) (hereinafter, “Dr. Jeffrey Testimony”)), quoted in AR 038 (DAB Decision). Yet, Dr. Jeffrey did not receive this data because Plaintiff’s subordinate Dr. Ruby herself inaccurately combined the buprenorphine-only

tablet and Suboxone Tablet rates, passing it off as the RADARS data, to falsely state that the RADARS data showed that Suboxone Film had the lowest rate in the state (when, really, the data showed that buprenorphine-only tablets did). AR 545, ¶ 27 (Information); *see* AR 038 (DAB Decision). Dr. Jeffrey testified that if Dr. Ruby had sent the accurate RADARS data showing that Suboxone Film had a greater rate of pediatric exposure than the tablets (including buprenorphine-only tablets),<sup>26</sup> then he “would have stopped any process to change [MassHealth’s] policy decision around the film.” AR 691 (Dr. Jeffrey Testimony), *quoted in* AR 038 (DAB Decision). Dr. Jeffrey also testified that MassHealth ultimately “made a change in [its] policy around Suboxone Film,” and the data provided by Dr. Ruby “was the pivot point upon which [MassHealth] made that decision.”<sup>27</sup> AR 690 (Dr. Jeffrey Testimony); *see* AR 037 (DAB Decision) (referencing this testimony). Dr. Jeffrey’s testimony supports the DAB’s nexus conclusion.

Plaintiff forwards two final arguments to undermine the nexus found by DAB, both unavailing. First, Plaintiff argues that the DAB “failed to consider” MassHealth’s 2016 expansion decision, wherein it granted Suboxone Film preferred drug status. Pl.’s Resp. 19. But the DAB *did* consider MassHealth’s 2016 decision and found it to be irrelevant. AR 031 (DAB Decision). The DAB concluded that “it was MassHealth’s decision in December 2012<sup>[28]</sup> to expand access to

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<sup>26</sup> Plaintiff cites a 2013 study to argue that “the exposure to the film was not, in fact, greater than the exposure to the tablet.” Pl.’s Resp. 20 (citing AR 485 (citing EJ Lavonas et al., *Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine by Young Children*, 163 J. PEDIATRICS 1377 (2013))). The Court fails to see how this study, post-dating both MassHealth’s 2012 expansion and the conduct underlying Plaintiff’s conviction, is relevant to the present question and provides a basis for reversal on substantial evidence review.

<sup>27</sup> Plaintiff makes much of a section of Dr. Jeffrey’s testimony where he said that he “d[idn’t] know if it would have made a change in the decision,” AR 691 (Dr. Jeffrey Testimony), to argue that “Dr. Jeffrey repeatedly refused to say that Dr. Ruby’s presentation of the data had any effect on MassHealth’s decision to expand coverage of Suboxone Film,” Pl.’s Mem. Supp. 29 (citing AR 691 (Dr. Jeffrey Testimony)). But the “it” to which Dr. Jeffrey was referring when he said he “d[idn’t] know if it would have made a change in the decision” was the “difference of 2.7 for Suboxone [F]ilm versus 3.3 for Suboxone [T]ablets.” AR 691 (Dr. Jeffrey Testimony). Dr. Jeffrey was not discounting the importance of the *combined-tablet number* he received from Dr. Ruby; and in any event, Dr. Jeffrey said that the 2.7-to-3.3 difference “would have mattered.” *Id.*

<sup>28</sup> This was a decision that was made based on Plaintiff’s direct subordinate’s false and misleading statements to MassHealth in October and November 2012, which Plaintiff subsequently failed to promptly correct. AR 038.

Suboxone Film . . . that formed the predicate for [Plaintiff’s] misbranding conviction” and the requisite nexus for § 1320a-7(a)(1) purposes. *Id.* The DAB found that “[t]he fact that Suboxone Film, under different factual circumstances, became a preferred product under the MassHealth program years after the events resulting in [Plaintiff’s] conviction does not change the fact that the drug was initially marketed to MassHealth using false and misleading data.” *Id.* The Court discerns no reversible error in the DAB’s conclusion that the 2016 expansion decision was irrelevant to Plaintiff’s 2012 conviction forming the basis for his exclusion.

Second, Plaintiff argues that the DAB “misidentifie[d] the cause of MassHealth’s 2012 decision to expand beneficiary access to Suboxone Film.” Pl.’s Resp. 19. Plaintiff cites to MassHealth’s prescriber letter which, according to Plaintiff, “made clear” that MassHealth relied on accurate national data in its decision. *Id.*; see Pl.’s Mem. Supp. 27–28. But the DAB found that “MassHealth never ‘stated that it relied only on the accurate data’” and that the December 2012 letter “did not purport to catalog all the information MassHealth considered in reaching its decision.” AR 036 (DAB Decision). The DAB further noted that Plaintiff “was convicted of drug misbranding despite MassHealth’s reference to nationwide pediatric exposure data in its December 2012 letter,” and “it was his failure to prevent or promptly correct [RBP]’s dissemination of false and misleading state-specific data to MassHealth that led to [his] misbranding conviction.” *Id.* (citing AR 547, ¶ 32 (Information)). The Court finds no reversible error here either.

For these reasons, the Court finds that substantial evidence in the record supports the Agency’s decision to exclude Plaintiff pursuant to § 1320a-7(a)(1).<sup>29</sup>

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<sup>29</sup> The Court notes that Plaintiff couches all the arguments addressed in this section as arguments that the DAB’s factual findings were arbitrary and capricious under the APA. Though that is the wrong standard of review to judge whether there was sufficient factual support for the DAB’s findings, the result would be the same under the arbitrary and capricious standard because when it comes to reviewing agency fact-finding, “the difference between the substantial evidence standard and the arbitrary and capricious standard [i]s ‘largely semantic.’” *Akinjiola v. Holder*, 2014 WL 641702, at \*6 (D. Md. Feb. 14, 2014) (quoting *Wash. Metro. Area Transit Auth. v. Loc. 689, Amalgamated Transit Union*, 818 F. Supp. 2d 888, 897 (D. Md. 2011)); see also *Ass’n of Data Processing Serv. Orgs.*,

### C. Plaintiff's Mandatory Exclusion Was Not an Arbitrary and Capricious Departure from Past Agency Practice

Lastly, the Court considers, and rejects, Plaintiff's contention that his mandatory exclusion was an unjustified departure from HHS precedent.

"[A]gencies are under an obligation to follow their own regulations, procedures, and precedents, or provide a rational explanation for their departures." *Jewell Smokeless Coal Corp. v. Looney*, 892 F.2d 366, 368 n.5 (4th Cir. 1989) (quoting *Nat'l Conservative Pol. Action Comm. v. Fed. Election Comm'n*, 626 F.2d 953, 959 (D.C. Cir. 1980)). Thus, "[i]f an agency follows 'by settled course of adjudication[] a general policy by which its exercise of discretion will be governed, an irrational departure from that policy' constitutes grounds for reversal." *De Leon v. Holder*, 761 F.3d 336, 344 (4th Cir. 2014) (quoting *INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996)). Relatedly, it is "a fundamental norm of administrative procedure" that an agency must "treat like cases alike." *Westar Energy, Inc. v. Fed. Energy Regul. Comm'n*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). But if an agency can "offer[] a 'reasoned explanation'" for "depart[ing] from its own precedent," *De Leon*, 761 F.3d at 344 (quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)), or if the agency can "point to a relevant distinction between the two cases" to show that two cases are not alike, *Westar Energy, Inc.*, 473 F.3d at 1241, then the agency action is not arbitrary and capricious on that ground.

Plaintiff proffers two bases to reverse the Secretary's decision as an arbitrary and capricious departure. First, he argues that *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012), demonstrates that his RCO misdemeanor misbranding conviction should be subject only to

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*Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 683–84 (D.C. Cir. 1984) (Scalia, J.) ("When the arbitrary or capricious standard is performing that function of assuring factual support, there is no *substantive* difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a 'nonarbitrary' factual judgment supported only by evidence that is not substantial in the APA sense[.]" (emphasis in original)).

permissive exclusion, not mandatory exclusion. Pl.’s Mem. Supp. 24–25. Second, Plaintiff contends that the Secretary went back on Agency policy by finding the mandatory exclusion applicable “in the absence of any restitution payment.” *Id.* The Court addresses each in turn.

1. *Friedman v. Sebelius* Does Not Render Plaintiff’s Exclusion Arbitrary and Capricious

Plaintiff at times frames his argument as one that *Friedman* created a clear “policy” that the Secretary can only ever subject RCO misdemeanor misbranding offenses to permissive exclusion. *See, e.g.*, Pl.’s Resp. 14 (Plaintiff listing this as a “*de facto* polic[y]” from which the Secretary allegedly departed). But based on the substance of Plaintiff’s contentions, the “policy” moniker makes little conceptual sense. The real thrust of Plaintiff’s argument is that this case is factually indistinguishable from *Friedman*, and thus the Secretary acted arbitrarily by finding Plaintiff subject to mandatory exclusion here when the *Friedman* executives received a different, permissive-exclusion fate. *See* Pl.’s Mem. Supp. 24–25; Pl.’s Resp. 13–15. There is no valid assertion of any broader “policy” in this respect.<sup>30</sup> Accordingly, the Court construes Plaintiff’s argument on this point as one challenging the Secretary’s mandatory exclusion decision on the ground that the Secretary has acted arbitrarily and capriciously by failing to “treat like cases alike.” *Westar Energy, Inc.*, 473 F.3d at 1241.

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<sup>30</sup> For example, Plaintiff does not point to any arguments made by the Secretary in *Friedman* that RCO misdemeanor misbranding offenses could never, under any circumstances, be subject to mandatory exclusion. Nor does Plaintiff point to anything in the court’s holding in *Friedman* requiring the same.

Plaintiff tries to categorize the RCO misdemeanor misbranding-based permissive exclusion in *Friedman* as creating a broader “policy” by linking it with the Secretary’s “longstanding interpretation” “of ‘related to,’” at issue in that case. Pl.’s Mem. Supp. 24 (quoting Br. Appellees 12, *Friedman v. Sebelius*, 2011 WL 5240481); Pl.’s Resp. 14 (quoting the same). But any analysis of “relat[e] to” in a vacuum does not decide the threshold question of whether the particular facts of a case fit into the relevant mandatory exclusion provision or Plaintiff’s preferred permissive exclusion provision, since, as already discussed, both provisions use “relat[e] to.” *See* 42 U.S.C. § 1320a-7(a)(1) (“criminal offense related to the delivery of an item or service”); *id.* § 1320a-7(b)(1)(A) (“consisting of a misdemeanor relating to fraud”).

At bottom, Plaintiff only cites to *Friedman* and its facts—just that one case—to demonstrate this purported “policy” of only subjecting RCO misbranding misdemeanants to permissive exclusion. A single case does not strike the Court as the sort of “*settled course of adjudication*[]” that gives something “general policy” status. *See De Leon*, 761 F.3d at 344 (emphasis added).

The Court rejects this argument for the same reasons that the DAB did. The DAB considered this argument and found that “the facts and circumstances in *Friedman* are materially distinguishable from the facts and circumstances of [Plaintiff’s] offense.” AR 043 (DAB Decision). “Specifically,” the DAB explained, “*Friedman* did not involve an entity’s direct misrepresentations to a state Medicaid program, so that the program would expand access to its misbranded drug.” *Id.* “The misbranding offense in *Friedman* was not directed at any particular health care plan and involved the delivery of a misbranded drug without regard to any particular health care program.” *Id.* (citing *Friedman*, 686 F.3d at 816).

The Court finds this a relevant, appropriate distinction. In this case, Plaintiff was convicted based on his failure to prevent and promptly correct false and misleading statements made *directly* to a state health care program, MassHealth, to get a drug approved for that program—and the criminal information in this case reflects as much. AR 542–47, ¶¶ 20, 23–24, 27–32 (Information). The *Friedman* misdemeanor misbranding convictions were based on those executives’ “admitted failure to prevent Purdue’s fraudulent marketing of OxyContin” generally. *Friedman*, 686 F.3d at 816. The criminal information in *Friedman* accordingly lacked *any* allegation that the misbranded products had a *direct* connection to Medicare or any state health program. *See* Information, *United States v. Perdue Frederick Co.*, No. 1:07-cr-29 (W.D. Va. May 10, 2007), ECF No. 5, at 1–16.<sup>31</sup> Suffice it to say that the Agency has provided the Court “a ‘reason[ed] explanation,’” *De Leon*, 761 F.3d at 344 (quoting *F.C.C. v. Fox*, 556 U.S. at 515), as to why Plaintiff’s RCO misdemeanor misbranding offense is “related to the delivery of an item or service under [a federal] or under a

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<sup>31</sup> Plaintiff seeks to bridge the factual gap by pointing to “an attachment to the plea agreement that led to the exclusion in *Friedman*.” Pl.’s Resp. 14. But Plaintiff all but admits that this argument fails by recognizing that the *Friedman* executives did not admit to the contentions in that attachment and “only stipulated to the allegations in the information.” *Id.* at 14–15.



State health care program,” 42 U.S.C. § 1320a-7(a)(1). Moreover, the facts of *Friedman* do not squarely map on and bind the Secretary otherwise.<sup>32</sup>

2. Plaintiff Fails to Establish a Longstanding Agency Policy of Requiring Restitution for Mandatory Exclusion to Apply

Plaintiff insists that “[f]or decades, the Secretary has required evidence of a restitution payment or forfeiture order before concluding that a conviction for misdemeanor misbranding was ‘program related.’” Pl.’s Mem. Supp. 25. Through two briefs, though, Plaintiff musters just two quotes (both employed only parenthetically) from DAB decisions to purportedly support this powerful claim. *See id.* at 25–26. Neither quote proves Plaintiff’s point. One quote reads: “In exclusion cases, restitution has long been considered a reasonable measure of program loss and evidence of the nexus between the offense and the program to which restitution is to be made.” *Linda Schmidt*, DAB No. CR3746, 2015 WL 1881612, at \*9 (H.H.S. Mar. 31, 2015). Another is a quote finding the requisite § 1320a-7(a)(1) nexus “[b]ased on Petitioner’s restitution and the records from his underlying conviction.” *Martin G. Hoffmeister, D.P.M.*, DAB No. CR3973, 2015 WL 3941469, at \*3 (H.H.S. June 19, 2015).

All that these quotes prove is that restitution can be a proper consideration to establish the required common-sense connection; they do not prove that restitution is necessary to establish that connection. Just because restitution was paid in some cases where mandatory exclusion applied does not make it a prerequisite to mandatory exclusion. Plaintiff has pointed to no DAB opinion

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<sup>32</sup> Plaintiff quotes some of the Secretary’s brief in *Friedman* in an apparent attempt to argue that the Secretary made admissions there that disprove any factual distinction between *Freidman* and this case when it comes to the applicability of a mandatory or permissive exclusion. *See* Pl.’s Mem. Supp. 25 (quoting Br. Appellees 48, *Friedman v. Sebelius*, 2011 WL 5240481). But the quoted portions of that brief were not addressing whether the offenses were “related to . . . any State health care program” under § 1320a-7(a)(1) or even if they were “relat[ed] to fraud” under § 1320a-7(b)(1)(B). Rather, the quoted portions addressed only the subsequent question (one not at issue here) of whether the facts triggered the aggravating factor in 42 C.F.R. § 1001.201(b)(2)(i) for “convictions caus[ing] losses to federal and state governments far exceeding \$5,000.” Br. Appellees 48, *Friedman v. Sebelius*, 2011 WL 5240481.




specifically stating that restitution is required for someone to be excluded under § 1320a-7(a)(1)—likely because there is no discernable basis for any such restitution requirement in the text of § 1320a-7(a)(1). Relatedly, Plaintiff has also provided no DAB opinion to support his contention that the fact that there were “no losses or victims associated with [Plaintiff’s] conduct” “undermines the statutory basis for mandatory exclusion” in this case. Pl.’s Mem. Supp. 27. Plaintiff thus has demonstrated no “policy” of *requiring* restitution for § 1320a-7(a)(1) exclusion to apply, and thus he has failed to demonstrate that the Secretary broke from any such policy in this case.

#### IV. CONCLUSION

None of Plaintiff’s theories provide a basis for the Court to grant Plaintiff the relief he seeks here. The Court finds no error in the Agency’s interpretation of 42 U.S.C. § 1320a-7(a)(1) in this case. There is sufficient evidence in the record to support the Agency’s factual findings. And Plaintiff has not persuaded the Court that his mandatory exclusion is an arbitrary and capricious departure from past practice. The Court will thus grant in full Defendants’ Motion for Summary Judgment and deny in full Plaintiff’s Motion for Summary Judgment.

An appropriate Order will accompany this Memorandum Opinion.

  
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Roderick C. Young  
United States District Judge

Richmond, Virginia  
Date: February 14, 2024